

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

PANDOL, *et al.*

Serial No.: 10/824,597

Filed: 15 April 2004

For: COMPOSITIONS COMPRISING PLANT-DERIVED
POLYPHENOLIC COMPOUNDS AND INHIBITORS OF
REACTIVE OXYGEN SPECIES AND METHODS OF
USING THEREOF

Confirmation No.: 7147

Art Unit: 4173

Examiner: Pagonakis, Anna

Atty. Dckt: 034044.021CIP1 (2002-
428-2)

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Mail Stop AF

Dear Sir:

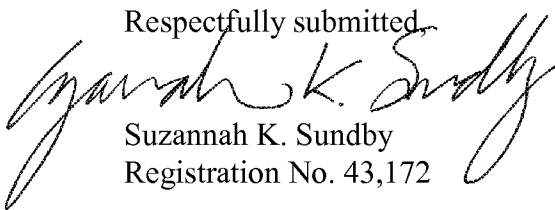
Applicant(s) respectfully request(s) review of the final rejection in the above-identified application. No amendments are being filed with this request.

This Request is being filed with a Notice of Appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

I am the attorney of record.

Respectfully submitted,



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REASONS FOR REVIEW REQUEST

The Claimed Invention

The claimed invention is a method of treating or inhibiting pancreatitis or pancreatic cancer in a subject which comprises a therapeutically effective amount of rottlerin (claim 37) or a derivative thereof (having the structural formula set forth in claim 47) to the subject.

The Issues

1. Improper withdrawal of claims based on election by original prosecution

Whether the Examiner improperly withdrew claims 47-57 as not being elected by original prosecution is improper where, as correctly noted by the Examiner, Applicants originally elected claims directed to “rottlerin or a derivative thereof”, and where Applicants canceled “or a derivative thereof” in the claims and added new claims 47-57 to contain the subject matter “or a derivative thereof” in the form of a chemical formula (as defined in the specification and previously argued) in order to address rejections under 35 U.S.C. 112, first and second paragraphs.

2. No reasonable expectation of success

Whether the Examiner improperly rejected the claims as being obvious under the TSM rational (G) exemplified in MPEP 2143 where the Examiner failed to establish a finding of a reasonable expectation of success.

The Law

ELECTION BY ORIGINAL PROSECUTION. If, after an Office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant will be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143 and 1.144. See 37 C.F.R. 1.145 (emphasis added).

REASONABLE EXPECTATION OF SUCCESS. Where an Examiner uses the Teaching, Suggestion or Motivation (TSM) rational (G) exemplified in the MPEP to support a conclusion of obviousness,

the Examiner must articulate a finding that there was a reasonable expectation of success. If this finding can not be made then the TSM rational (G) can not be used to support a conclusion of obviousness. See MPEP 2143; *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007), and *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006).

The Facts

1. IMPROPER WITHDRAWAL OF CLAIMS BASED ON ELECTION BY ORIGINAL PROSECUTION

In the Office action mailed 13 November 2008, the Examiner withdrew claims 47-57 based on election by original prosecution. However, as correctly noted by the Examiner, Applicants originally elected claims directed to “rottlerin or a derivative thereof” and had amended the claims and added new claims 47-57 to address various rejections under 35 U.S.C. 112, based on the phrase “or a derivative thereof”.

Specifically, in the Office action mailed 9 November 2007, the claims were rejected under 35 U.S.C. 112, second paragraph, as the Examiner deemed that the term “derivative” was unclear. In response, Applicants argued that the definition of “derivative” with respect to rottlerin was defined in the Specification on page 43, paragraph 171 and submitted that the claims were therefore clear and definite.

Then in the Office action mailed 25 June 2008, the claims were rejected under 35 U.S.C. 112, first paragraph, as lacking written description and enabling support. Specifically, the Examiner deemed that use of the term “derivative” in claims 37 and 46 fail to meet the provisions of 35 U.S.C. 112, first paragraph, as the claims lacked chemical structural information. In response, Applicants separated the rottlerin “derivative” out from claims 37 and 46 by canceling the term from the claims and adding new claims 47-57 in order to recite the structural formula provide on page 43 of the Specification in order to address the written description and enablement rejections.

Applicants respectfully submit that the scope and meaning of “a derivative” of rottlerin, as defined in the Specification on page 43, is in fact the same as the structural formula as set forth in claim 47. As such, the subject matter encompassed in claims 47-57 is not distinct and independent from the invention previously claimed. Therefore, Applicants respectfully submit

that it was improper to withdraw claims 47-57 under 37 C.F.R. 1.145.

2. NO REASONABLE EXPECTATION OF SUCCESS

The Examiner applies the teaching, suggestion, or motivation (TSM) rational to reject the claims as being obvious. In particular, see the Office action mailed 13 November 2008, page 4, last paragraph, where the Examiner states that “[o]ne of ordinary skill in the art would have a reasonable expectation of success that ... such success is expected since ...”.

Thus, the Examiner’s reasoning for rejecting the claimed invention as being obvious is as follows:

- a. Since Schwartz discloses that a PKC inhibitor can potentiate apoptosis in pancreatic tumor cells if administered with an antitumor therapeutic agent and Gschwendt teaches that rottlerin is a PKC inhibitor, it would have been obvious to use rottlerin to treat pancreatic cancer with a reasonable likelihood of success (in accordance with claim 20); and
- b. Since Mouria discloses that genistein stimulates apoptosis and caspase activation in pancreatic cancer cells, it would have been obvious to administer rottlerin with genistein in order to treat pancreatic cancer in accordance with claims 38-40.

However, the Examiner fails to articulate and support a finding that there was a reasonable expectation of success. In particular, the Examiner’s reasonable expectation of success rationale is based on the incorrect assertion that Schwartz teaches that all PKC inhibitors will be effective (e.g. induce apoptosis) against pancreatic cancer cells. The disclosure of Schwartz can not be used to support a finding of a reasonable expectation of success since **Schwartz actually teaches that the specific PKC inhibitors as tested do not induce apoptosis in cancer cells** when administered without a chemotherapeutic agent. See Schwartz which states that: (a) “safingol alone did not induce significant levels of apoptosis” (col. 7, lines 35-37), and (b) RO 32-0432 alone had “essentially no effect on inducing apoptosis” (col. 18, lines 48-49). Safingol and RO 32-0432 are known PKC inhibitors.

Thus, Schwartz does not teach or suggest that all PKC inhibitors will be effective against cancer cells. Since (1) Schwartz does not teach or suggest that all PKC inhibitors will be

effective against cancer cells, (2) Schwartz and Mouria do not make any mention of rottlerin, and (3) Gschwendt does not make any mention of pancreatic cancer or pancreatitis an essential legal finding for establishing a prima facie case of obviousness based on the TSM rationale is missing. That missing essential legal finding is a reasonable expectation of success.

Since the Examiner has failed to establish a finding that there was a reasonable expectation of success, a prima facie case of obviousness based on the TSM rationale can not be made.

In view of the above and the Affidavit of Dr. Jingzhen Yuan which supports a finding that the claimed invention is unobvious, Applicants respectfully request that the review panel rejoins claims 47-57 and allows claims 37-46 and 47-57 (or reopens prosecution). If the review panel reopens prosecution, Applicants would appreciate a proposed amendment if appropriate.